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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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00/225,502 01/06/99 MOORE P PF392

022195  
HUMAN GENOME SCIENCES INC  
9410 KEY WEST AVENUE  
ROCKVILLE MD 20850

HM12/0815

EXAMINER

DECLoux, A

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

08/15/01

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

**Advisory Action**Application No.  
**09/225,502**

Applicant(s)

**Moore, P. et al**

Examiner

**DeCloux, Amy**

Art Unit

**1644**

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED Jul 23, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**THE PERIOD FOR REPLY [check only a) or b)]**

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

4. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see attached sheet.
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 21-56 and 58-103
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other: \_\_\_\_\_

### Detailed Action

1. Applicant's after-final request for reconsideration, delivered 7-23-01(Paper No. 22), is acknowledged.

Claims 21-56 and 58-103 are currently pending.

2. In view of applicant's after-final request for reconsideration, the objection to the specification made in the previous office action mailed 10-27-99, is withdrawn. However, the 101 and 112 first rejections are maintained.

3. **Maintained** Claims 21-56 and 58-103 stand rejected under 35 U.S.C. 101 because the claimed invention lacks a substantial, specific, or well-established utility.

4. Applicant traverses the rejection and disagrees with the examiner's contention that the asserted utility of the claimed polynucleotides and corresponding polypeptides is neither specific nor substantial based merely on homology to FKBP65, and asserts that Wilson teaches that at least 40% identity corresponds to a sharing of a precise function, while sequence identities of about 25% comprise a functional class. However, the examiner contends that Wilson's definition of "functional class" and "precise function" is rather broad especially when the function of non-enzymatic proteins are compared, as evidenced by the second paragraph on page 243, which says that the non-enzyme classes are broader for precise function. For example, on page 244, Figure 6c shows that a protein involved in starch metabolism has the same precise function as a protein in glycogen metabolism, and page 242, column 2, the second to the last paragraph says that arc repressor and c-jun have the same precise function because both are transcription factors. However, as one of skill in the art would not know how to use any transcription factor without knowing its specificity, similarly one of skill in the art would not know how to use the claimed nucleotides which encode polypeptides that have only a limited probability of functioning in a relatively broad classification. Given Wilson's broad functional classes and given a BLAST search shows that the overall homology of the recited amino acid sequences of SEQ ID NO:6 and SEQ ID NO:8 is less than 50% identical with FKBP65 which binds a potent immunosuppressant FK506, the examiner disagrees with applicant's contention that said low sequence homology provides sufficient specific and substantial utility for the proteins encoded by said SEQ ID NO:s being used for the treatment of diseases caused by overactive immune systems, especially in view of the lack of any functional guidance in the instant specification(other than sequence homology). Therefore though applicant's arguments have been carefully considered they are not deemed persuasive and the rejection is maintained, essentially for the reasons of record.

5. **MAINTAINED** Claims 38-51 and 68-80 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant traverses the written description rejection on the basis that 95% identity to SEQ ID NO:6 and 8 will inherently share some structural similarities, however the examiner contends that the instant specification does not disclose the structure sufficient for whatever immunosuppressant activity is purported to be displayed by the proteins of SEQ ID NO:6 or 8. Applicant further argues that one of skill in the art could make mutations in the polynucleotides encoding SEQ ID NO:6 or 8 to achieve a protein with 95% homology to SEQ ID NO:6 or 8 that still retains the function of SEQ ID NO: 6 or 8, which may be true if in fact one knew the functional activity of SEQ ID NO:6 or 8 in the first place. Applicant suggests that the variants of SEQ ID NO:6 and 8 could be tested for by the PPLase activity as described by Galat et al, but the instant specification does not disclose that SEQ ID NO:6 or 8 itself displays said activity.

Therefore though applicant's arguments have been carefully considered they are not deemed persuasive and the rejection is maintained, essentially for the reasons of record.

6. **MAINTAINED** Claims 38-51 and 68-80 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant traverses the enablement rejection on the grounds that " since the disclosed or otherwise known methods of making and screening the claimed polypeptides may be used to determine without undue experimentation , whether a given polypeptide or variant thereof encompassed by the claims exhibits, for example, PPLase activity, the enablement requirement is fully satisfied." However, the examiner points out that the instant specification discloses insufficient guidance that the polypeptides of SEQ ID NO:6 or 8, or variants thereof, exhibit PPLase activity, or any other activity for that matter. Therefore, though the skill in the molecular biology is high as stated by the applicant, the examiner contends that the function the polypeptides of SEQ ID NO:6 or 8, or variants thereof, is unpredictable based on less than 50% homology with FKBP65 and it would require undue experimentation to practice the claimed invention in view of the insufficient guidance and direction in the instant specification on how to use said polypeptides, or variants thereof.

Therefore though applicant's arguments have been carefully considered they are

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not deemed persuasive and the rejection is maintained, essentially for the reasons of record

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner  
Group 1640, Technology Center 1600  
August 15, 2001

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182/644